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(54) Dialysis device and method of making the same.

(57) A mass transfer device of the type used, e.g., for blood dialysis is made by winding on a mandrel (20) a series of fiber strands (24), each of which consists of a solid fiber (26) and one or more hollow fibers (22), the solid fiber being at least as large, and preferably substantially larger, in diameter than the hollow fiber. As the strands are wound on the mandrel they are temporarily anchored at spaced locations along the mandrel by beads of a liquid pre-potting compound which eventually harden into solid anchor plates (32). When the winding is complete, the mandrel is cut at each anchor plate to form individual temporary cartridges which can withstand the handling required in washing and drying. After each individual cartridge is final-potted, the anchor plates (32) are discarded, and the final potting is cut in a conventional manner to form manifold surfaces at each end of the cartridge. A deburring treatment is then applied to the manifold surface at each end of the cartridge to smooth out any microscopic irregularities of the manifold surface which can cause thrombogenesis.

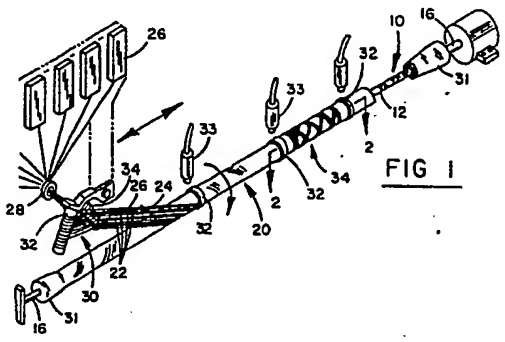

FIG 1

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MASS TRANSFER DEVICE AND METHOD OF MAKING THE SAME

This invention relates to mass transfer devices such as blood dialysis cartridges.

Mass transfer devices such as blood dialysis cartridges or the like are conventionally made from bundles of parallel semipermeable hollow fibers through which blood is caused to flow while the fibers are immersed in dialysate. A common problem of these devices is the tendency of the fibers to bunch or mat together so that the free flow of dialysate over the entire surface of the fibers is substantially impaired. The resulting flow of mass transfer efficiency slows down the dialysis process and is economically wasteful.

It has been proposed (U.S. Patents No. 3,422,008 and 3,794,468) to wind hollow fibers on a mandrel to form a dialysis cartridge. This method alleviates the bunching problem to some degree. However, the hollow semipermeable fibers used in blood dialysis equipment are quite delicate and cannot be wound with a great deal of tension for fear of damage. They also

tend to be limp and floppy when in use. Consequently, the dialysis fibers have considerable freedom of movement and are still somewhat subject to bunching under the fluid flow forces of the dialysate. In addition, when the hollow fibers in the prior art devices bunch in a radial direction with respect to the mandrel, there is a danger that they may pinch each other at crossovers.

As suggested by the aforesaid U.S. patent 3,422,008, it is desirable to wind a plurality of cartridges from continuous fibers on a single mandrel and to provide "tubesheets" at intervals along the mandrel where cuts can subsequently be made to form manifold surfaces at which the interior of the hollow fibers is accessible.

Experience has shown, however, that the "tubesheets" applied during the winding make a poor bond with the fibers, mostly because the fibers as wound are oily and wet. It is therefore not practical to use "tubesheets" in the final dialysis cartridge.

In addition, the prior art blood dialysis devices tend to be thrombogenic, i.e. they tend to cause blood clotting which must be counteracted by medication, and which in a significant number of cases makes the patient intolerant of this type of equipment.

The invention overcomes the above problems of the prior art by winding the fibers in strands consisting

of one or more hollow active fibers and a thicker, solid spacer fiber laid down parallel to each other.

If the strand is wound with sufficient tension to cause successive layers to lie firmly against each other, this arrangement results in the formation of a cage-like structure with continuous protective channels defined by the solid fibers. The smaller hollow fibers lie loosely in those channels and are supported by the solid fibers of the layer below them to prevent them from pinching the hollow fibers of the layer below.

As a practical matter, the fragile nature of the hollow fibers makes it advisable to wind the strand rather loosely. When this is done, the solid fibers of successive layers become spaced from one another and no longer form a solid cage. However, although the hollow fibers can then move beyond the confines of the channel in which they are supposed to lie, the spacer fibers generally still tend to prevent them from wandering very far out of line. In this manner, the spacer fibers effectively prevent bunching of the hollow fibers, both radially and tangentially.

Inasmuch as it is desirable, when winding dialysis cartridges, to produce a plurality of cartridges in a single winding, beads of resinous adhesive are deposited on the mandrel during the winding operation, each bead being spaced from the next by one cartridge

length. These beads harden into solid temporary anchor plates similar to the "tubesheets" of U.S. patent 3,422,008 which hold the fibers in place, and through which the wound mandrel can eventually be cut to form individual temporary cartridges which are strong enough to withstand the handling involved in washing and drying the fibers (to remove inherent moisture and organic oil preservative introduced into the fibers during manufacture).

Following the assembly of the temporary cartridges into appropriate housings by a conventional final-potting process (in which the potting material forms a solid, fluid-tight bond with the dry fibers), the temporary anchor plates are cut off and discarded, and a cut is made through the final potting to form a manifold surface at which the interior of the hollow fibers is accessible without significant leakage.

In accordance with the invention, thrombogenesis can be largely prevented by rounding the edges of the fiber walls where they protrude through the manifold surface, to eliminate microscopic burrs or sharp irregularities and debris on the manifold surface on which clotting can start. The invention achieves this in a preferred embodiment by depositing onto the manifold surface a meniscus-forming solution of polyurethane which is then cured to form a thin, smooth, lacquer-like layer which smooths out any microscopic surface irregularities but does not clog the open ends of the hollow fibers.

Fig. 1 is a schematic perspective view, partly cut away, showing the winding operations involved in the manufacture of blood dialysis cartridges in accordance with the invention;

Fig. 2 is an axial section along line 2-2 of Fig. 1;

Fig. 3 is an elevational view, partly in section, showing the final potting step of the inventive method;

Fig. 4 is an enlarged vertical section of a portion of Fig. 3 along line 4-4;

Fig. 5 is a schematic elevational view illustrating the manifold surface treatment of the invention;

Fig. 6 is an enlarged slice-type vertical section of a portion of the manifold surface following treatment, as indicated by line 6-6 of Fig. 5; and

Fig. 7 is an enlarged view of the fiber strand pattern laid down by the winding apparatus of Fig. 1.

Best Mode For Carrying Out The Invention

In accordance with a preferred embodiment of the invention, an apertured basket-weave core 10 is first formed in accordance with any well-known commercial technique, as for example by molding or by passing a ribbon 12 of Dacron fibers or other suitable material through an epoxy bath (not shown) and winding it on a winding stick 16 in the criss-cross pattern best illustrated in Fig. 2 to a thickness of about one millimeter. For the purpose of this invention, the rigid basket-weave core 10 is used in sections slightly shorter than the eventual length of a finished blood dialysis cartridge.

The cut sections of core 10 are now slipped back onto winding stick 16 (Fig. 2), but this time the core sections 10 are separated from one another by plastic spacers 18 of the same inside diameter but preferably somewhat greater outside diameter. The winding stick 16, core sections 10, and spacers 18 together form a mandrel 20 onto which the hollow semipermeable dialysis fibers 22 can be wound.

As best shown in Figs. 1 and 7, one or more fiber strands 24 each consisting of a thick, solid spacer fiber 26 and one or more hollow dialysis fibers 22 are would side-by-side onto the mandrel 20 of Fig. 2. Any conventional technique for laying down the fiber strands 24 in the pattern shown in detail in Fig. 7 may be used. As an example, the individual fibers may be brought from creels 26 (Fig. 1) through a feed eye 28 which is mounted for reciprocating lengthwise movement along the mandrel 20. Between the feed eye 28 and the mandrel 20, the fibers are drawn through a comb 30 extending between a pair of inclined, generally cylindrical guides 32, 34. The guides 32,34 in conjunction with the comb 30, assure that the individual fibers of fiber strands 24 are laid down on the mandrel 20 parallel to each other and properly spaced from one another.

The fiber pattern produced by the foregoing method is illustrated in an enlarged scale in Fig. 7. It will be noted that adjacent spacer fibers 261B, 262B of the middle layer B in Fig. 3 form a protective channel between them in which the smaller (or at least no thicker), delicate dialysis fibers 221B, 222B, 223B and 224B can lie without fear of being pinched by the crossing fibers of layers A and C.

The spacer fibers 26 have an additional function which makes their presence desirable, in accordance with the invention, regardless of whether or not the strands 24 are tightly wound. The spacer fibers 26 are preferably made of a relatively stiff, chemically inert material such as nylon, and their diameter may be about (e.g.) 300 microns. By contrast the dialysis fibers 22 are typically made of high-purity cellulose with an outside diameter about 200 microns, which makes them floppy and not very straight. Because they cannot be wound very tightly, they have considerable freedom of lateral movement in the absence of spacer fibers 26, and they tend to bunch together when dialysate is caused to flow across them. This bunching, in turn, substantially reduces their mass transfer efficiency and impedes the dialysis process.

The provision of spacer fibers 26 in accordance with this invention tends to restrict lateral movement of the dialysis fibers 22 even when the strands 24 are rather loosely wound. The dialysis fibers 22 tend to stay substantially within the channels defined by adjacent spacer fibers 26, and detrimental bunching of the dialysis fibers 22 is thereby eliminated or at least substantially reduced.

The winding method shown in Fig. 1 forms waste portions 31 of significant length at each end of the mandrel 20 where the winding direction of the strands 24 is reversed at the end of each pass of the feed eye 28. It is therefore economically necessary to wind a substantial number of cartridges on a single mandrel to keep the percentage of waste within tolerable limits.

To this end, beads 32 of a hardenable liquid resin such as epoxy are applied to the fiber strands 24 from guns 33 at spaced locations along the mandrel 20 as they are wound. The locations of beads 32 coincide with the locations of spacers 18 along mandrel 20. The epoxy beads 32 adhere to the spacers 18 and to the fibers of strands 24, and as the beads 32 harden, they form solid anchor plates which firmly secure the fibers 22 and 26 in fixed positions at spaced intervals along the mandrel 20. However, the anchor plates do not, and are not intended to, form fluid-tight bonds with the fibers of strands 24. Consequently, as pointed out hereinafter, they cannot serve as manifolds in the finished cartridge.

When the desired number of winding passes have been made, a flexible basket-weave retaining net 34 (Fig. 1) may be wound over the fiber strands 24 between the beads 32, using a Dacron or other chemically inert ribbon coated with just enough epoxy to cause successive layers of ribbon to stick to each other without becoming rigid.

With the anchor plates 32 having hardened, the mandrel 20 with the fiber strands 24 wound thereon is now removed from the winding stick 16, and cuts are made along lines 36 (Fig. 2) to separate the individual cartridges. The anchor plates 32, after cutting, co-act with the spacers 18 and the core sections 10 to form a sufficiently rigid temporary cartridge structure to allow the partly completed cartridges to be handled for washing, drying and storage.

Because of the fact that the anchor plates 32 do not bond sufficiently well to the unwashed and undried fibers of strands 24, during the winding process, they cannot be used to provide a fluid-tight seal between the interior of the finished cartridge and the blood manifold (not shown) with which the interior of the hollow fibers 22 communicates in the finished device. Consequently, a final-potting step has to be performed to assemble the temporary cartridge assembly with the outer housing 38 of the finished cartridge after the fibers have been washed and dried.

This may be done in any convenient way, but in the preferred embodiment of the invention, as illustrated in Figs. 3 and 4, the temporary cartridge assembly is placed, one end at a time, into a mold 40 attached to the cradle 42 of a centrifuge 44. A riser tube 46 with openings 48 at its lower end is placed into the core 18, and an appropriate amount of a conventional polyurethane potting compound 50 (Fig. 4) is poured into the tube 46.

The centrifuge 44 is then turned on and the resulting centrifugal force swings cradle 42 about hinge 52 to a horizontal position. At the same time, the centrifugal force evenly distributes the potting compound 50 over the lower (now outer) end of the cartridge to permanently anchor the fibers and form a fluid-tight seal around the fibers and with the outer housing 38.

After the final potting operation has been repeated for the other end of the cartridge, and the ends of the cartridge have been cut off along line 54 (Fig. 4) to remove and discard the now useless anchor plates 32, the cartridge is ready for assembly, in a conventional manner, into a dialysis unit (not shown).

As previously stated herein, it has been observed that cut fiber dialysis cartridges tend to produce thrombogenesis in the patient. In accordance with this invention, this problem is overcome by rounding the microscopic sharp edges or burrs left by the cutting operation at the end of the hollow dialysis fibers 22 where they protrude from the manifold surface 58 (Fig. 6).

In accordance with the preferred embodiment of the invention, the manifold surface 58 (Figs. 5 and 6) of potting compound 50 is made non-thrombogenic by the process illustrated in Fig. 5. As shown in that figure, the cartridge 60 is slowly rotated for two or three revolutions under a fogging nozzle 62 which deposits an extremely fine mist (e.g. 10-20 micron droplet size) of polyurethane solution 64 (in the preferred embodiment, a solution consisting of 8% by weight Estane 5715 manufactured by B.F. Goodrich, 42% by weight of cellulose acetate, and 50% by weight of methyl ethyl ketone is used to advantage) onto the surface 58. The surface tension of the polyurethane solution causes it to form a meniscus 66 (Fig. 6) which covers any sharp edges of the dialysis fibers 22 without penetrating excessively into the interior of the fibers. The meniscus 66 is preferably cured into a hard, smooth surface similar to a lacquer by the application of warm, dry air and exposure for a few minutes to an infrared heat lamp.

In addition to rounding the entrances to the hollow interior of fibers 22, the cured polyurethane solution smooths the surface 58 and encapsulates any snags or debris 68 from the cutting process that may still be present after the conventional cleaning of the surface 58 following the cutting step.

The range of polyurethane content of the solution which can be used for the purposes of this invention is determined by the fact that lower percentages of Estane, though feasible, are increasingly wasteful of solvent and spraying time, and that an Estane content of 10% or more by weight tends to make the solution viscous to form a satisfactory meniscus, whereupon the hollow fiber ends start to plug.

The choice of solvent is, of course, not limited to the above-mentioned solvents, as the solvents act only as a volatile carrier. Consequently, any medically acceptable volatile solvent compatible with the polyurethane could be

used. Other types of varnish which adhere to the fibers and header material can be used provided the surface produced is relatively non-thrombogenic.

CLAIMS:

1. A method of making a mass transfer device by winding fibers into a mandrel, characterized in that said fibers are wound in strands (24) each consisting of a solid fiber (26) and at least one hollow semipermeable fiber (22) no thicker than said solid fiber and parallel to said solid fiber.

2. A method according to claim 1 on which said hollow semipermeable fibers (22) are substantially thinner than said solid fibers (26).

3. A method according to claim 1 or claim 2 characterised in that a plurality of said strands (24) are simultaneously laid down in parallel relation to each other.

4. A mass transfer device made up of successive layers of fibers, the fibers of each layer being parallel to one another but disposed at an angle to the fiber of the next adjacent layers, characterised thereby that each layer consists of at least one

strand of fibers (24), each strand consisting of at least one solid fiber (26) and at least one hollow semipermeable fiber (22) no thicker than said solid fiber and parallel thereto.

5. A mass transfer device according to claim 4, in which said hollow semipermeable fibers (22) are substantially thinner than said solid fibers (26).

6. A mass transfer device according to claim 4 or claim 5 further characterized in that each strand (24) consists of one solid fiber (26) and a plurality of hollow fibers (22).

7. A method of making a mass transfer device by winding hollow semipermeable fibers onto a mandrel, applying beads of a hardenable liquid material at intervals along said mandrel to form anchor plates, and cutting said anchor plates after hardening to form individual temporary cartridges for washing and drying purposes, characterised in that said hardenable material (32) is removed from said cartridge after final potting.

8. A method according to claim 7, further characterised in that said hardenable liquid material (32) is a resin.

9. A method of making a mass transfer device for blood dialysis or the like, which includes the step of casting a final-potting manifold around the ends of hollow semipermeable fibers, and cutting said final potting to form a manifold surface, characterised in that said manifold surface is treated to round the ends of said fibers protruding through said manifold surface to make them non-thrombogenic.

10. A method of rendering the manifold surface of a cut pre-potted blood dialysis fiber bundle non-thrombogenic, characterised in that a hardenable, meniscus-forming solution is applied to said manifold surface after cutting and is cured into a smooth, hard coating.

11. A method according to claim 10, characterised in that said meniscus-forming solution is a polyurethane solution.

12. A method according to claim 11, characterised in that said polyurethane solution contains not more than 10% by weight of polyurethane and is applied to said manifold surface in a fine fogging spray.

13. A method according to claim 12, in which said polyurethane solution consists of about 8% by weight

of polyurethane and about 92% by weight of volatile solvents, and in which the droplet size of said spray is in the range of 10-20 microns.

14. A non-plugging, meniscus-forming solution for deburring blood manifold surfaces in hollow-fiber blood dialysis devices, consisting of not more than 10% by weight of polyurethane in a volatile solvent.

15. The method of making a blood dialysis cartridge or the like, comprising the steps of:

a) winding onto an apertured hollow mandrel (20) strands of fibers (24), said strands including a solid spacer fiber (26)and at least one hollow dialysis fiber (22) generally parallel thereto;

b) applying to said fibers, during the winding thereof, a hardenable adhesive material (32) adapted to hold said fibers in a fixed position at spaced locations along said mandrel;

c) allowing said adhesive material to harden;

d) cutting through said hardened adhesive material at said spaced locations (36) to form individual temporary cartridges;

e) final-potting the ends of said temporary cartridges to fit into a housing in sealing relationship,

f) cutting through said final-potted ends to remove said adhesive material and expose the ends

of said fibers in a manifold surface; and

g) treating the exposed ends of said fibers and said manifold surface with a meniscus-forming hardenable substance to produce a smooth non-thrombogenic surface on said fiber ends and manifold.

16. A method according to claim 15, in which said final potting is done centrifugally.

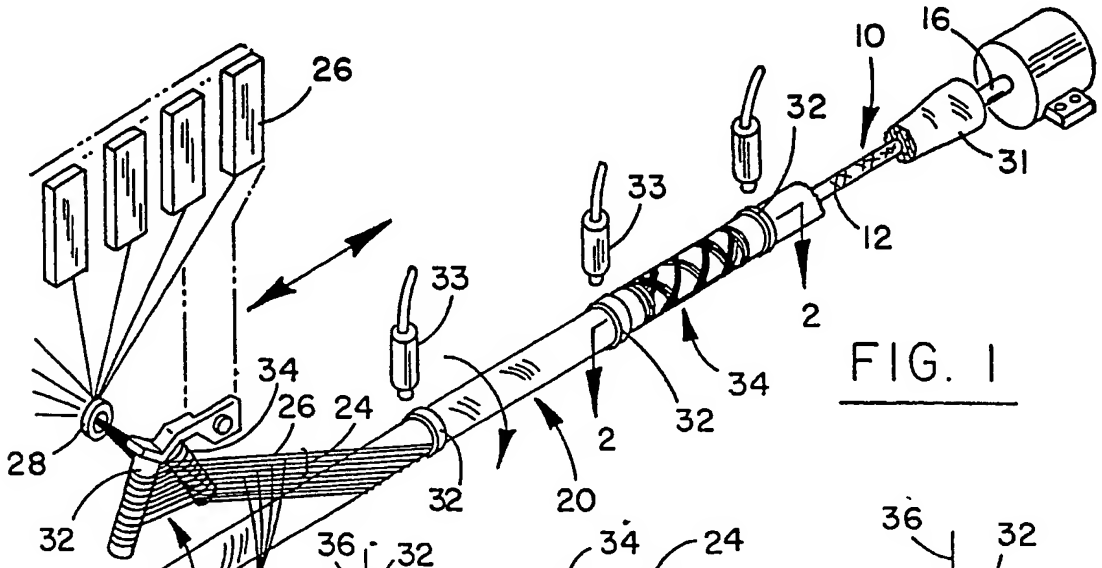

FIG. 1

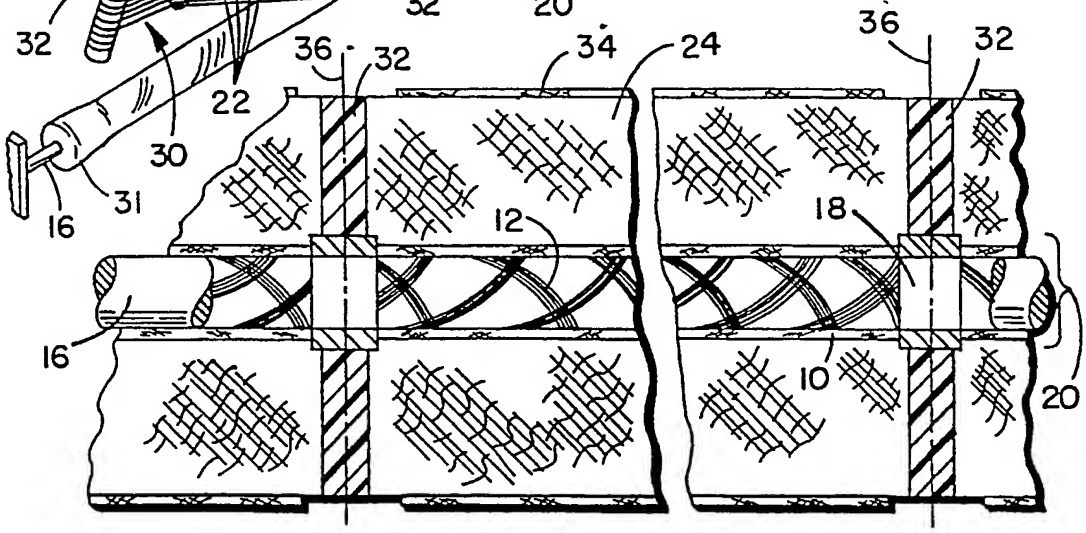

FIG. 2

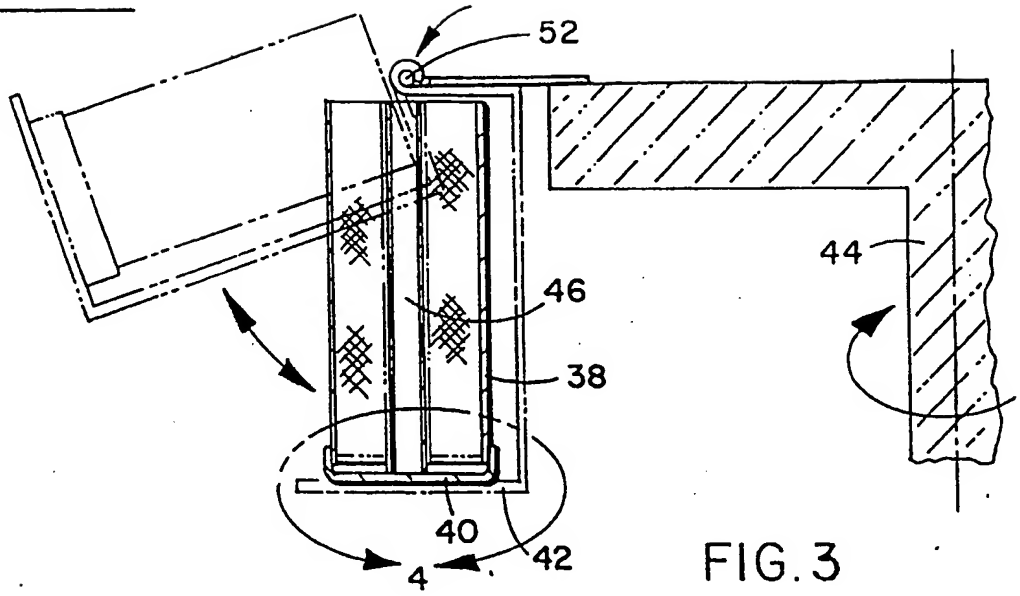

FIG. 3

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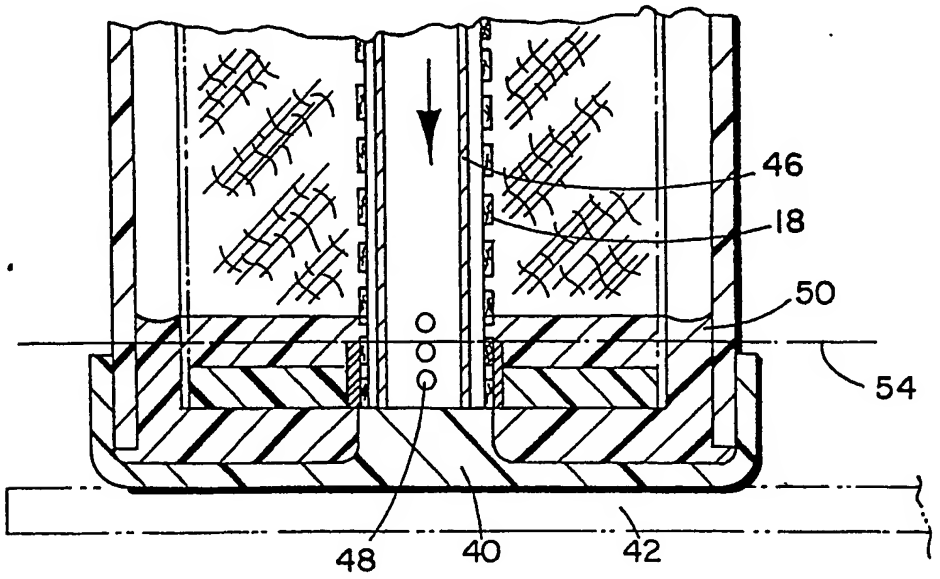

FIG. 4

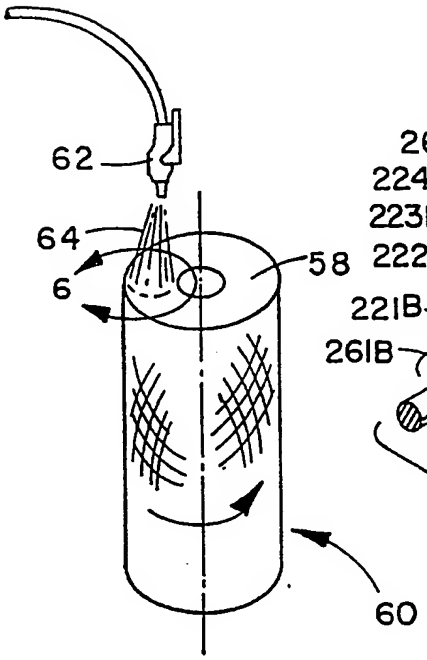

FIG. 5

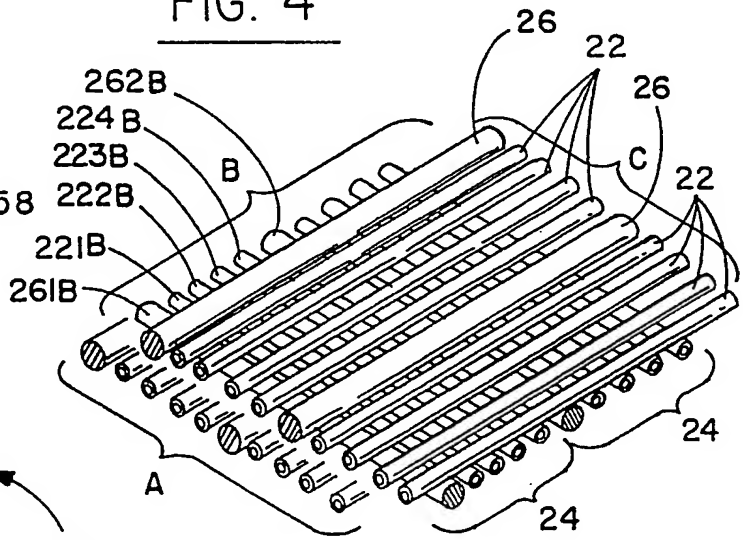

FIG. 7

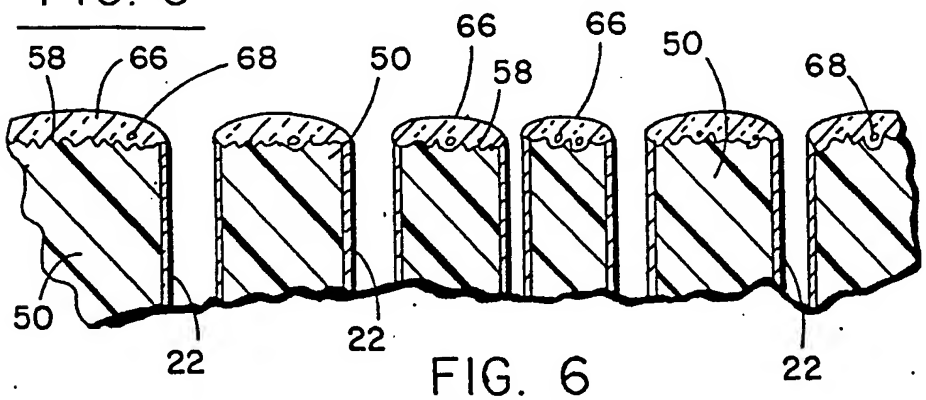

FIG. 6

European Patent Office

EUROPEAN SEARCH REPORT

Application number

EP 80 30 1143.6

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.³)
P	DE - A1 - 2 900 603 (TOYO BOSEKI) * claims 5, 7 to 10; page 16, line 32; fig. 1, 2, 4, 7, 8 *	1,3,4, 7-11, 15	B 01 D 13/00 //A 61 M 1/03
A	US - A - 3 503 515 (V.J. TOMSIC) * complete document *		
A	US - A - 4 140 637 (C.W. WALTER) * complete document *		TECHNICAL FIELDS SEARCHED (Int.Cl.³)
A	DE - A1 - 2 721 444 (FRESENIUS) * complete document *		A 61 M 1/03 B 01 D 13/00

CATEGORY OF CITED DOCUMENTS

- X: particularly relevant
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- O: non-written disclosure
- P: intermediate document
- T: theory or principle underlying the invention
- E: conflicting application
- D: document cited in the application
- L: citation for other reasons
- &: member of the same patent family, corresponding document

X The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Berlin	13-06-1980	KÜHN

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